EFFECTIVE DATE NOTE: At 80 FR 29904, May 22, 2015, §640.27 was removed, effective May 23, 2016.

Subpart D—Plasma

§ 640.30 Plasma.

(a) *Proper name and definition.* The proper name of this component is Plasma. The component is defined as:

(1) The fluid portion of one unit of human blood intended for intravenous use which is collected in a closed system, stabilized against clotting, and separated from the red cells; or

(2) The fluid portion of human blood intended for intravenous use which is prepared by apheresis methods as specified in the directions for use for the blood collecting, processing, and storage system including closed and open systems.

(b) *Source.* (1) Plasma shall be obtained by separating plasma from blood collected from blood donors or by plasmapheresis.

(2) Plasma may be obtained from a unit of Whole Blood collected by another licensed establishment.

[42 FR 59878, Nov. 22, 1977; 48 FR 13026, Mar. 29, 1983, as amended at 50 FR 4139, Jan. 29, 1985; 72 FR 45888, Aug. 16, 2007]

§ 640.31 Suitability of donors.

(a) Whole blood donors shall meet the criteria for donor suitability prescribed in §640.3.

(b) Plasmapheresis donors shall meet the criteria for donor suitability prescribed in §640.63, excluding the phrase ''other than malaria'' in paragraph (c)(9) of that section. Informed consent shall be required as prescribed in §640.61.

[42 FR 59878, Nov. 22, 1977, as amended at 64 FR 45372, Aug. 19, 1999]

EFFECTIVE DATE NOTE: At 80 FR 29904, May 22, 2015, §640.31 was revised, effective May 23, 2016. For the convenience of the user, the revised text is set forth as follows:

§ 640.31 Eligibility of donors.

(a) Whole Blood donors must meet the criteria for donor eligibility prescribed in §§630.10 and 630.15 of this chapter.

(b) Collection establishments must determine the eligibility of plasmapheresis donors in accordance with §§630.10 and 630.15 of this chapter.

§ 640.32 Collection of source material.

(a) Whole Blood must be collected, transported, and stored as prescribed in §640.4. When whole blood is intended for Plasma, Fresh Frozen Plasma, and Liquid Plasma, until the plasma is removed, the whole blood must be maintained at a temperature between 1 and 6 °C or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, Center for Biologics Evaluations and Research. Whole blood intended for Platelet Rich Plasma must be maintained as prescribed in §640.24 until the plasma is removed. The red blood cells must be placed in storage at a temperature between 1 and 6 °C immediately after the plasma is separated.

(b) Plasma obtained by plasmapheresis shall be collected as prescribed in §§640.62, 640.64 (except that paragraph (c)(3) of §640.64 shall not apply), and §640.65.

[42 FR 59878, Nov. 22, 1977, as amended at 45 FR 27927, Apr. 25, 1980; 50 FR 4139, Jan. 29, 1985; 64 FR 45372, Aug. 19, 1999; 72 FR 45888, Aug. 16, 2007]

EFFECTIVE DATE NOTE: At 80 FR 29905, May 22, 2015, §640.32(b) was amended by removing ''§§640.62, 640.64,'' and adding in its place ''§640.64'', effective May 23, 2016.

§ 640.33 Testing the blood.

(a) Blood from which plasma is separated shall be tested as prescribed in §610.40 of this chapter and §640.5 (a), (b), and (c).

(b) Manufacturers of Plasma collected by plasmapheresis shall have testing and recordkeeping responsibilities equivalent to those prescribed in §§640.71 and 640.72.

[42 FR 59878, Nov. 22, 1977, as amended at 44 FR 17658, Mar. 23, 1979; 50 FR 4139, Jan. 29, 1985; 53 FR 117, Jan. 5, 1988; 66 FR 31165, June 11, 2001]

EFFECTIVE DATE NOTE: At 80 FR 29905, May 22, 2015, §640.33(a) was amended by removing ''§640.5(a), (b),'' and adding in its place ''§640.5(b)'', effective May 23, 2016.

§ 640.34 Processing.

(a) *Plasma.* Plasma shall be separated from the red blood cells and shall be stored at −18 °C or colder within 6

hours after transfer to the final container or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system unless the product is to be stored as Liquid Plasma.

(b) *Fresh Frozen Plasma.* Fresh frozen plasma shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and minimal manipulation of the donor's tissue. The plasma must be separated from the red blood cells or collected by an apheresis procedure, and placed in a freezer within 8 hours or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system, and stored at −18 °C or colder.

(c) *Liquid Plasma.* Liquid Plasma shall be separated from the red blood cells and shall be stored at a temperature of 1 to 6 °C within 4 hours after filling the final container or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system.

(d) *Platelet Rich Plasma.* Platelet rich plasma shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and manipulation of the donor's tissue. The plasma shall be separated from the red blood cells by centrifugation within 4 hours after completion of the phlebotomy or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system. The time and speed of the centrifugation shall have been shown to produce a product with at least 250,000 platelets per microliter. The plasma shall be stored at a temperature between 20 and 24 °C immediately after filling the final container. A gentle and continuous agitation of the product shall be maintained throughout the storage period, if stored at a temperature of 20 to 24 °C.

(e) *Modifications of Plasma.* It is possible to separate Platelets and/or Cryoprecipitated AHF from Plasma. When these components are to be separated, the plasma shall be collected as described in § 640.32 for Plasma.

(1) Platelets shall be separated as prescribed in subpart C of part 640, prior to freezing the plasma. The remaining plasma may be labeled as ''Fresh Frozen Plasma,'' if frozen within 6 hours after filling the final container or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system.

(2) Cryoprecipitated AHF shall be removed as prescribed in subpart F of part 640. The remaining plasma shall be labeled ''Plasma, Cryoprecipitate Reduced.''

(3) Plasma remaining after both Platelets and Cryoprecipitated AHF have been removed may be labeled ''Plasma, Cryoprecipitate Reduced.''

(f) *The final container.* (1) The final container shall have no color added to the plastic and shall be transparent to permit visual inspection of the contents; any closure shall maintain a hermetic seal and prevent contamination of the contents.

(2) The final container material shall not interact with the contents, under the customary conditions of storage and use, in such a manner as to have an adverse effect upon the safety, purity, potency, and effectiveness of the product.

(3) Prior to filling, the final container shall be identified by number so as to relate it to the donor.

(g) *The final product.* (1) The final product shall be inspected immediately after separation of the plasma and shall not be issued for transfusion if there is (i) any abnormality in color or physical appearance, or (ii) any indication of contamination.

(2) With the exception of Platelet Rich Plasma and Liquid Plasma the final product shall be inspected for evidence of thawing or breakage at the time of issuance, however, the containers need not be stored in a manner that shows evidence of thawing if records of continuous monitoring of the storage temperature establish that the temperature remained at −18 °C or colder. If continuous monitoring of the product is not available, the final product shall be stored in a manner that will show evidence of thawing and shall not be issued if there is any evidence of thawing.

(3) No preservative shall be added to the final product.

[42 FR 59878, Nov. 22, 1977, as amended at 43 FR 34460, Aug. 4, 1978; 48 FR 13026, Mar. 29, 1983; 50 FR 4139, Jan. 29, 1985; 64 FR 45373, Aug. 19, 1999; 66 FR 1836, Jan. 10, 2001; 66 FR 40890, Aug. 6, 2001; 72 FR 45888, Aug. 16, 2007]

Subpart E [Reserved]

Subpart F—Cryoprecipitate

§ 640.50 Cryoprecipitated AHF.

(a) *Proper name and definition.* The proper name of this product shall be Cryoprecipitated AHF. The product is defined as a preparation of antihemophilic factor, which is obtained from a single unit of plasma collected and processed in a closed system.

(b) *Source.* The source material for Cryoprecipitated AHF shall be plasma which may be obtained by whole blood collection or by plasmapheresis.

[42 FR 21774, Apr. 29, 1977; 48 FR 13026, Mar. 29, 1983, as amended at 50 FR 4139, Jan. 29, 1985]

§ 640.51 Suitability of donors.

(a) Whole blood donors shall meet the criteria for suitability prescribed in § 640.3.

(b) Plasmapheresis donors shall meet the criteria for suitability prescribed in § 640.63, excluding the phrase ''other than malaria'' in paragraph (c) (9) of that section. Informed consent shall be required as prescribed in § 640.61.

[42 FR 21774, Apr. 29, 1977, as amended at 64 FR 45373, Aug. 19, 1999; 73 FR 49942, Aug. 25, 2008]

EFFECTIVE DATE NOTE: At 80 FR 29905, May 22, 2015, § 640.51 was revised, effective May 23, 2016. For the convenience of the user, the revised text is set forth as follows:

§ 640.51 Eligibility of donors.

(a) Whole blood donors must meet the criteria for eligibility prescribed in §§ 630.10 and 630.15 of this chapter.

(b) Collection establishments must determine the eligibility of plasmapheresis donors in accordance with §§ 630.10 and 630.15 of this chapter.

§ 640.52 Collection of source material.

(a) Whole blood used as a source of Cryoprecipitated AHF shall be collected as prescribed in § 640.4. Whole blood from which both Platelets and Cryoprecipitated AHF is derived shall be maintained as required under § 640.24 until the platelets are removed.

(b) If plasmapheresis is used, the procedure for collection shall be as prescribed in §§ 640.62, 640.64 (except that paragraph (c)(3) of that section shall not apply), and 640.65.

[42 FR 21774, Apr. 29, 1977, as amended at 50 FR 4139, Jan. 29, 1985; 64 FR 45373, Aug. 19, 1999]

EFFECTIVE DATE NOTE: At 80 FR 29905, May 22, 2015, § 640.52(b) was amended by removing ''§§ 640.62, 640.64,'' and adding in its place ''§ 640.64'', effective May 23, 2016.

§ 640.53 Testing the blood.

(a) Blood from which plasma is separated for the preparation of Cryoprecipitated AHF shall be tested as prescribed in § 610.40 of this chapter and § 640.5 (a), (b), and (c).

(b) The tests shall be performed on a sample of blood collected at the time of collecting the source blood, and such sample container shall be labeled with the donor's number before the container is filled.

(c) Manufacturers of Cryoprecipitated AHF obtained from plasma collected by plasmapheresis shall have testing and record-keeping responsibilities equivalent to those prescribed in §§ 640.71 and 640.72.

[42 FR 21774, Apr. 29, 1977, as amended at 42 FR 37546, July 22, 1977; 42 FR 43063, Aug. 26, 1977; 50 FR 4139, Jan. 29, 1985; 53 FR 117, Jan. 5, 1988; 66 FR 31165, June 11, 2001]

EFFECTIVE DATE NOTE: At 80 FR 29905, May 22, 2015, § 640.53(a) was amended by removing ''§ 640.5(a), (b),'' and adding in its place ''§ 640.5(b)'', effective May 23, 2016.

§ 640.54 Processing.

(a) *Processing the plasma.* (1) The plasma shall be separated from the red blood cells by centrifugation to obtain essentially cell-free plasma.

(2) The plasma shall be placed in a freezer within 8 hours after blood collection or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system. A combination of dry ice and organic solvent may be used for freezing: *Provided,* That the procedure